K020672 AUG 0 5 2002

510(k) Summary - ELECSYS® Anti-Tg on ELECSYS® Immunoassay Analyzers

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3831

Contact person: Sherri L. Coenen

Date prepared: February 27, 2002

Device Name

Proprietary name: ELECSYS® Anti-Tg Assay

Common name: Antibodies to thyroglobulin (Anti-Tg)

Classification name: Thyroid autoantibody immunological test system

Device description

The ELECSYS® Anti-Tg Assay a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

510(k) Summary - ELECSYS® Anti-Tg on ELECSYS® Immunoassay Analyzers, continued

Intended use	Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma.
Indication for use	The Anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases.
Substantial equivalence	The ELECSYS Anti-Tg test is equivalent to other devices legally marketed in the United States. We claim equivalence to the DPC Immulite 2000 Anti-TG AB (K991094).

510(k) Summary - ELECSYS® Anti-Tg on ELECSYS® Immunoassay Analyzers, continued

Substantial equivalence - similarities

The following table compares the ELECSYS® Anti-Tg, with the Predicate Devices.

Feature	New Device ELECSYS Anti-Tg	Predicate Device Immulite 2000 Anti-TG Ab
Intended use	Immunoassay for the in vitro determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and Modular Analytics E170 immunoassay analyzers.	For in vitro diagnostic use with the Immulite 2000 analyzer – for the quantitative measurement of autoantibodies to thyroglobulin (TG) in serum EDTA and heparinized plasma, as an aid in the clinical diagnosis of thyroid diseases.
Sample type	Human serum Human plasma treated with sodium heparin, or K_2/K_3-EDTA	human serum, EDTA, and heparinized plasma
Assay Protocol	competitive assay	immunometric assay
Detection Protocol	electrochemiluminescence immunoassay	chemiluminescence assay
Traceability	Calibrated against NIBSC 65/93 Standard	Calibrated against NIBSC 65/93 Standard

510(k) Summary - ELECSYS® Anti-Tg on ELECSYS® Immunoassay Analyzers, continued

Substantial equivalence – differences

The following table compares the ELECSYS® Anti-Tg with the Predicate Device.

Feature	New Device ELECSYS Anti-Tg	Predicate Device Immulite 2000 Anti-TG Ab
Measuring range	10 – 4000 IU/ml	0 – 3000 IU/ml
Expected values	Up to 115 IU/ml (95th percentile)	Nondetectable to 40 IU/ml (95th percentile)
Instrument	ELECSYS® 2010, 1010, and Modular Analytics E170 Immunoassay Analyzers	Immulite 2000 Analyzer

Substantial equivalence – performance characteristics

The performance characteristics of the ELECSYS Anti-Tg and the Predicate Device are compared in the table below.

Reproducibility was determined using Elecsys reagents, pooled human sera and commercial controls according to a modified protocol (EP5-A) of the NCCLS: five or six times daily for 10 days (n = 59 or 60); intra-assay precision on E170, n = 21. The following results were obtained:

Feature	New Device ELECSYS Anti-Tg	Predicate Device Immulite 2000 Anti-TG Ab
Intra-assay precision (%CV)	Human Serum • 4.9% at 62.8 IU/ml • 5.1% at 115 IU/ml • 4.6% at 290 IU/ml • 5.6% at 2894 IU/ml	• 4.9% at 43 IU/ml • 3.2% at 92 IU/ml • 3.5% at 205 IU/ml • 4.0% at 324 IU/ml • 3.7% at 508 IU/ml • 3.9% at 736 IU/ml
	Controls • 5.5% at 99.5 IU/ml • 5.6% at 232 IU/ml	
Total precision (%CV)	Human Serum • 8.7% at 62.8 IU/ml • 7.2% at 115 IU/ml • 5.9% at 290 IU/ml • 6.3% at 2894 IU/ml	• 5.7% at 23 IU/ml • 4.6% at 63 IU/ml • 5.0% at 201 IU/ml • 5.8% at 381 IU/ml • 5.0% at 784 IU/ml • 5.7% at 1644 IU/ml
	Controls • 7.2% at 99.5 IU/ml • 6.7% at 232 IU/ml	

510(k) Summary - ELECSYS® Anti-Tg on ELECSYS® Immunoassay Analyzers, continued

Substantial equivalence – performance characteristics, continued

The performance characteristics of the ELECSYS anti-Tg and the Predicate Device are compared in the table below.

Feature	New Device ELECSYS Anti-Tg	Predicate Device Immulite 2000 Anti-TG Ab
Analytical sensitivity	< 10 IU/ml	2.2 IU/ml
Limitations	• No interference from icterus up to 66 mg/dL • No interference from hemolysis up to 1.69 g/dL • No interference from lipemia up to 2000 mg/dL triglyceride • No interference from biotin up to 60 ng/mL • No interference from rheumatoid factor up to 300 U/mL	• No significant effect from bilirubin. • No significant effect from hemolysis.
On-board stability	• Elecsys® 2010 / E170: 6 weeks • Elecsys® 1010: 6 weeks (stored alternately in refrigerator and analyzer at ambient temperature 20-25 C) Up to 20 hr. opened in total	N/A

510(k) Summary - ELECSYS® Anti-Tg on the ELECSYS® Immunoassay Analyzers, continued

Substantial equivalence – performance characteristics, continued

The performance characteristics of the ELECSYS Anti-Tg and the Predicate Device are compared in the table below.

Feature	New Device ELECSYS Anti-Tg	Predicate Device Immulite 2000 Anti-TG Ab

Calibration frequency	• Elecsys® 2010 / E170:
	  • Once per reagent lot
	  • after one month (using the same reagent lot)
	  • after 7 days (using the same reagent kit on the analyzer)
	• Elecsys® 1010
	  • With every reagent kit
	  • after 7 days (using the same reagent kit, ambient temperature 20 - 25°C)
	  • after 3 days (using the same reagent kit, ambient temperature 25 - 32°C)
	• Controls out of range (both systems)
		Every 2 weeks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

AUG 0 5 2002

Re: k020672
Trade/Device Name: ELECSYS® Anti-Tg Assay
Regulation Number: 21 CFR § 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: II
Product Code: JZO
Dated: May 9, 2002
Received: May 13, 2002

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A K020672

Device Name: ELECSYS® Anti-Tg Test System

Indications For Use:
Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid disease.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys® 1010 / 2010 and Modular Analytics E170 (Elecsys module) Immunoassay Analyzers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

J P Reves for S. Attaie

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020672